

## **Summary of Studies Supporting USDA Product Licensure**

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	16F1.21
True Name	Feline Rhinotracheitis-Calici-Chlamydia Psittaci Vaccine, Modified Live Virus, Modified Live Chlamydia
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	May 17, 2019

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

124 16F1.21 Page 1 of 5

Study Type	Efficacy
Pertaining to	Feline Calicivirus
Study Purpose	Demonstrate efficacy against feline calicivirus
<b>Product Administration</b>	Intramuscularly (IM)
Study Animals	Cats
<b>Challenge Description</b>	
Interval observed after	
challenge	
Results	Results applicable to subcutaneous (SQ) route of administration.  Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	December 19, 1990

124 16F1.21 Page 2 of 5

Study Type	Efficacy
Pertaining to	Chlamydia psittaci (Chlamydophila felis )
Study Purpose	Demonstrate efficacy against Chlamydia psittaci (Chlamydophila
	felis)
<b>Product Administration</b>	Intramuscularly (IM) or Subcutaneously (SQ)
Study Animals	Cats
<b>Challenge Description</b>	
Interval observed after	
challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	March 18, 1991

124 16F1.21 Page 3 of 5

Study Type	Efficacy
Pertaining to	Feline rhinotracheitis virus
Study Purpose	Efficacy against feline rhinotracheitis virus
<b>Product Administration</b>	Intramuscularly (IM)
Study Animals	Cats
<b>Challenge Description</b>	
Interval observed after	
challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	July 14, 1989

124 16F1.21 Page 4 of 5

Study Type	Safety
Pertaining to	ALL
Study Purpose	Demonstrate safety under field conditions
<b>Product Administration</b>	Intramuscularly (IM) or Subcutaneously (SQ)
Study Animals	Cats
<b>Challenge Description</b>	
Interval observed after	
challenge	
Results	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
USDA Approval Date	Unknown

124 16F1.21 Page 5 of 5